DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 6 1999 1717 '99 APR -7 P1:30

Michael Bergelson, Ph.D.
President
Paceart Associates, L.P.
81 Two Bridges Road, Building 2
Fairfield, New Jersey 07004

Ref: 98P-1227

Dear Mr. Bergelson:

This is in response to your letter dated December 21, 1998 in which you requested a variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables. Your request covers two devices, the Cardiovoice Telephone and the "Heart Access Plus" Cardiac Event Recorder. Your request asks the FDA to allow the continued manufacture and sale of these devices until new devices can be designed. You anticipate that this could take until May 11, 2001.

It is our understanding that the design of the Cardiovoice Telephone and the "Heart Access Plus" Cardiac Event Recorder precludes compliance with the Performance Standard for Electrode Lead Wires and Patient Cables. For the Cardiovoice Telephone to comply with this performance standard, the current jacks would need adapters affixed permanently in the receptacles, either mechanically or with glue. However, if this were done, the Cardiovoice could no longer be used as a telephone to transmit voice messages during the ECG transmission. The patient would require both a standard telephone and a coupler, which would defeat one of the principle reasons for using the Cardiovoice Telephone. A similar condition exists for the "Heart Access Plus" Cardiac Event Recorder.

Since adapters cannot be used to convert the existing Cardiovoice Telephone, I am granting a temporary variance with regard to existing electrode lead wires used with those Cardiovoice Telephones shipped prior to May 11, 1998. Non-compliant lead wires that were in user facilities prior to May 11, 1998, and intended for use with the Cardiovoice Telephone, may continue to be used with this device until May 11, 2001. In addition, non-compliant replacement lead wires may be provided to user facilities for those Cardiovoice Telephone shipped prior to May 11, 1998, either by your firm or by other third-party lead wire suppliers. However, prior to May 11, 2001, each user facility must discontinue use of those non-compliant lead wires. They will need to either replace or convert their remaining devices to accept lead wires that comply with the standard. The extended transition time should allow for removal of many devices through normal attrition, and allow user facilities sufficient time to schedule and budget for new devices or to retrofit their devices to permit use of compliant lead wires.

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As a condition of granting this temporary variance the FDA requests that you notify your customers of the specific provision of this variance, any retrofit options that are available, and the obligation to be in full compliance with the performance standard by May 11, 2001. That letter should issue to your customers within 45 days of your receipt of this letter, with a copy submitted to the Office of Compliance, HFZ-340, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

I am denying your request for variance for any Cardiovoice telephones that were shipped on or after May 11, 1998. These devices were required to be in compliance with the performance standard as of that date. Please notify FDA of the status of all Cardiovoice telephones that were marketed on or after May 11, 1998, and what actions you will take to remedy the noncompliance for those devices.

It is our understanding that the "Heart Access Plus" Cardiac Event Recorder was exported but was never marketed in the United States. Devices that do not comply with a performance standard may be exported under provisions of section 802 of the Federal Food, Drug, and Cosmetic Act. Therefore, a variance is not needed for the "Heart Access Plus" Cardiac Event Recorder, and I am denying that part of your variance request.

I trust that this response addresses your concerns. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

for Elizabeth D. Jacobson, Ph.D.
Acting Director
Center for Devices and Radiological Health